

**Responses to Major Comments on
Technical Support Document**

**Public Health Goal
For
1,3-Dichloropropene
In Drinking Water**

Prepared by

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INTRODUCTION

The following are responses to major comments received by the Office of Environmental Health Hazard Assessment (OEHHA) on the proposed public health goal (PHG) technical support document for 1,3-dichloropropene as discussed at the PHG workshop held on October 6, 1998, or as revised following the workshop. Some commenters provided comments on both the first and second drafts. For the sake of brevity, we have selected the more important or representative comments for responses. Comments appear in quotation marks where they are directly quoted from the submission; paraphrased comments are in italics.

These comments and responses are provided in the spirit of the open dialogue among scientists that is part of the process under Health and Safety Code Section 57003. For further information about the PHG process or to obtain copies of PHG documents, visit the OEHHA web site at www.oehha.org. OEHHA may also be contacted at:

Office of Environmental Health Hazard Assessment
301 Capitol Mall, Room 205
Sacramento, California 95814
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RESPONSES TO MAJOR COMMENTS RECEIVED

Dow AgroSciences LLC

Comment 1: “Dow AgroSciences has reviewed the ‘draft’ document on the ‘Public Health Goal for 1,3-D in Drinking Water.’ We have identified many key studies and assessments that need to be added to your document and used in your PHG calculation. These scientific studies and assessments are critical to arriving at an appropriate PHG for 1,3-D. This letter will give you a list of these studies and assessments and an analysis of their importance to the overall PHG number.”

Regarding the toxicology and carcinogenicity of 1,3-D, the commenter states: “Reviewing the PHG document it has been noted that several critical studies were not reviewed. Most of these studies are relatively new and have only recently been submitted to the EPA or made public. These studies are particularly critical because the data indicates increased margins of safety associated with the agricultural use of 1,3-D over that in previous regulatory assessments of 1,3-D. This is especially the case with the new carcinogenicity study results.”

“We believe for the purpose of this drinking water assessment, the 23 studies listed must be considered.”

Response 1: We thank you for your submission of the names of studies not cited in the PHG document (and your subsequent submission of a number of the recent studies from Dow Chemical Company Reports). A review of the subjects covered in the studies indicates that some provide useful supplemental information. Where appropriate, additional text has been added to the PHG document. Specifically, a summary of the Kezic *et al.* (1996) study examining the dermal absorption and metabolism of 1,3-DCP in human volunteers has been added to the Metabolism and Pharmacokinetics section. Aspects of some of the other studies, however, are already presented in the PHG document, and their inclusion is beyond the scope of the PHG review. Given the brief time available for review of these materials, emphasis has been placed on those studies which appear in the peer-reviewed literature. None affects the dose-response evaluation or the calculation of the PHG value at this time.

Comment 2: *Regarding the environmental fate of 1,3-D, the commenter states:* “In addition, there are also 16 environmental fate studies focusing on water, air, and soil that are also not included in your document. Again these are very recent studies. Each of these studies were evaluated as part of the USEPA’s reregistration and Special Review evaluation. Again, if OEHHA is going to conduct a comprehensive assessment, it should take into account exposures from sources including, air, water, and soil and these studies will be critical for such an assessment.”

“A complete list of studies is provided in the appendix.”

Response 2: Thank you for identifying these materials relevant to the exposure assessment of 1,3-dichloropropene. Such materials would be relevant for a comprehensive assessment and may be useful for establishing or modifying the relative source contribution (RSC) for the non-cancer dose-response evaluation. The PHG value for 1,3-DCP is based on a cancer endpoint, so this information would not be expected to have an impact on the currently recommended number. Since these materials are not as yet available in their entirety, their review will need to occur when the PHG for 1,3-DCP is reconsidered.

Comment 3: *Regarding unpublished risk assessments not presented in the PHG document:* “As a result of the new scientific findings in the most recent toxicology and carcinogenicity studies on 1,3-D (see Appendix), Dow AgroSciences undertook the task of getting the scientific opinions of an independent group of scientists about these studies. We had an independent organization, Toxicology Excellence for Risk Assessment (TERA), establish a panel of expert scientists to review these new results and interpret and summarize the meaning of the results. I have enclosed in this package the ‘Final Draft Document’ for review by the TERA panel of experts. This is an up to date assessment which also contains the deliberations of the expert TERA panel. The final report of the TERA panel on 1,3-D will be published soon.”

Response 3: We thank you for your submission of the draft TERA report and look forward to a review of the final published version. This document will become a part of the available materials when the PHG for 1,3-dichloropropene is reconsidered (within five years, by statute).

Comment 4: “In Summary, we request that rather than establishing a separate drinking water criterion for 1,3-D, OEHHA accept temporarily the values identified in the EPA RED document until the USEPA Cancer Peer Review panel carries out their reclassification review of 1,3-D in 1999.”

Response 4: We believe the evaluation presented in the PHG document presents the most appropriate public health-protective assessment of 1,3-dichloropropene at the present time. Products of activities such as those carried out by U.S. EPA will certainly be a part of future OEHHA analyses of the health effects of 1,3-dichloropropene for purposes of establishing a drinking water standard. In support of the PHG document, U.S. EPA’s recent Ambient Water Quality Criteria document (EPA/822/R-98/005; July 1998) identifies 1,3-DCP “likely to be carcinogenic to humans by all routes of exposure,” with a mutagenic mode of action. Furthermore, under the Safe Drinking Water and Toxic Enforcement Act of 1986, 1,3-DCP is listed as a chemical known to the State to cause cancer. The International Agency for Research on Cancer has classified 1,3-DCP as a Group 2B carcinogen. 1,3-DCP is listed in the National Toxicology Program’s seventh annual report on carcinogens as a compound “reasonably anticipated” to be a carcinogen. Consequently, there appears to be a substantial agreement in the scientific community that 1,3-DCP should be treated as a potential human carcinogen.